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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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DYKEMA GOSSETT PLLC
10 S. WACKER DR., STE. 2300
CHICAGO, IL 60606

EXAMINER	
SGAGIAS, MAGDALENE K	

ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,543	HOLM, PER SONNE	
	Examiner	Art Unit	
	MAGDALENE K. SGAGIAS	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-103* is/are pending in the application.

4a) Of the above claim(s) *55-103* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/22/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-103 are pending.

Applicant's election without traverse of group I in the reply filed on 7/22/08 is acknowledged.

Claims 55-103 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/22/08.

Claims 1-54 are under consideration.

Claim Objections

Claims 5, 6, 8, 9-24, 27-29, 32, 35-36, 39, 41-42, 44, 46-51, 54 are objected to under 37 CFR 1.75(c) as being in improper form because multiple dependent claims cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Claims 4-54 are objected to under 37 CFR 1.75(c) a being improper form because multiple dependent claims should refer to other claims in the alternative only.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5, 24-29, 32, 36, 47-48, 50-54 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Applicants

claim, in claims 1-5, an adenovirus, which can be a naturally occurring adenovirus, wherein the first protein is expressed prior to the second protein.

The claims reciting mutated adenoviruses wherein the E3 region (the elected region) is inactive read on naturally occurring adenovirus mutants.

Claims reciting adenoviruses with certain expression cassettes likewise reads on naturally occurring adenoviruses because the "expression cassettes" read on naturally occurring adenoviral promoter-polypeptide coding region expression cassettes. With regard to the adenovirus being capable of replicating in cells containing YB-1 in the nucleus independent of the cell cycle, it is noted that the claims read on naturally occurring adenoviruses which would be capable of replicating in cells with the recited YB-1 activity as this protein would not interfere with normal adenoviral replication. With regard to the claimed replication system, this reads on normal adenovirus replication and gene expression in infected cells, i.e. the system comprises a infected cell comprising an adenoviral nucleic acid which can have a naturally occurring mutation in an E1A or E1B region and additional adenoviral nucleic acids which lack this mutation and can have a helper function with regard to the missing gene activity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-17, 21-27, 29-34, 36-38, 46-54 are rejected under 36 U.S.C. 102(b) as being anticipated by **Hallenbeck et al** (US 5,998,205).

Applicants claim an adenovirus expressing a first protein which is selected from the group comprising an E1B protein, prior to a second protein which is selected from the group comprising an EIA-protein. Applicants also claim adenoviruses which comprise the E1A, or E1B genes under control of a heterologous promoter or functionally inactive E1A, or E1B genes. Applicants also claim adenoviruses which provide YB-1 in the nucleus through at least one adenoviral protein or that the provision of YB-1 in the nucleus is mediated through at least one adenoviral protein, whereby preferably the adenoviral protein is different from EIA.

The examiner is interpreting the claims as noted in the above 101 rejection. Hallenbeck et al. (See whole document, particularly Claims 1-20, columns 5-8, 10, etc.) teaches adenoviruses which comprise the E1B coding regions under control of heterologous promoters (can be tissue specific or tumor specific, etc.) and optionally comprising expression cassettes for expression of antisense or ribozyme sequences and apoptosis inducing genes (i.e. E1A or E4). With regard to the limitation that the claimed adenovirus provides YB-1 in the nucleus through at least one adenoviral

protein, it is noted that the adenoviral protein E1B-55k normally targets the YB-1 protein to the nucleus and this is an inherent property of the natural E1B-55k protein (See Holm et al., Journal of Biological Chemistry, March 2002, Vol. 277, No. 12, pp. 10427-10434) which would be present in the adenoviruses recited by Hallenbeck et al. and said YB-1 and E1B-55k normally act jointly to facilitate adenovirus replication. With regard to claim limitations reciting that the El, E3 or E4 regions are functionally inactive, Hallenbeck et al. teach functionally inactive E1 and E4 regions wherein the E1 or E4 coding regions are operably linked to promoters (i.e. tumor specific promoters) which are inactive in normal cells, rendering the genes functionally inactive in normal cells. The adenoviruses disclosed by Hallenbeck et al. can be classified as recombinant and/or mutant as they have modifications to the genome. Hallenbeck et al. therefore teaches the claimed invention.

Claims 39-40 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by **Irving et al** (US 20030095989).

Applicants claim an adenovirus comprising a nucleic acid encoding YB-1 under control of a promoter.

Irving et al. (published 5/22/2003, filed 12/17/2001, see whole document, particularly paragraph [0105]) recites generation of a adenoviral vector comprising the YB-1 encoding region under control of the CMV promoter/enhancer. Irving et al. therefore teaches the claimed invention.

Applicant cannot rely upon the foreign priority papers to overcome this rejection under 35 USC 102(a) because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 (and dependent claims) are vague in that applicants recite "the at least one protein is under control of a promoter". A protein cannot be under control of a promoter; however, a nucleic acid sequence encoding a protein can be under control of a promoter.

Claim 24 (and dependent claims) are vague in that claim 24 recites that the adenovirus comprises at least one functionally inactive adenoviral region, whereby the region is selected from the group comprising the E1 region, the E3 region, the E4 region and combinations thereof, while the claims depends from claim 1 which recites that the adenovirus can express E1B or E4 prior to expressing E1A. It is unclear how the same genes which are recited as being expressed in claim 89 are then functionally inactive in claim 24.

Statutory Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-3 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 89-91 of copending Application No. 10/531,366. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewiseextension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985); In re Van Omum, 686 F.2d 937,214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ'644 (CCPA 1969). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321 (d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 39-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 47-48 of copending Application No. 10/451,210 (hereafter the '210 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite an adenovirus comprising a nucleic acid sequence encoding YB-I. The instant claim 40 recites that the YB-1 sequence is under control of a promoter while the '210 claims do not explicitly recite a promoter for this sequence. However, it would have been obvious for the ordinary skilled artisan to operably link a promoter to the YB-1 coding sequence because expression of the YB-1 sequence is essential for operation of the adenoviral replication system recited in the '210 claims. If the YB-1 protein is not expressed, it makes no sense to include a nucleic acid sequence encoding it in the adenoviral vector. The claims are therefore obvious one over the other. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chang et al, (US 2004/0009588) teach an adenovirus expressing a protein which is selected from E1B and E1A.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571) 272-3305. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, Jr., can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Magdalene K. Sgagias, Ph.D.
Art Unit 1632

/Anne-Marie Falk/
Anne-Marie Falk, Ph.D.
Primary Examiner, Art Unit 1632